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| APPLICATION NUMBER | FILING OR 371 (c) DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|------------------------|-----------------------|------------------------|
| 10/813,801 | 03/30/2004 | Peter Serno | Le A 35249C1 |

35969
 JEFFREY M. GREENMAN
 BAYER PHARMACEUTICALS CORPORATION
 400 MORGAN LANE
 WEST HAVEN, CT 06516

CONFIRMATION NO. 7555
FORMALITIES LETTER

 OC000000012996900

Date Mailed: 06/22/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$ 770 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$380** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$1280** for a Large Entity

| |
|---|
| 08/05/2004 FFANIA2 00000052 133372 10813801 |
| 01 FC:1001 770.00 DA |
| 02 FC:1202 90.00 DA |
| 03 FC:1203 290.00 DA |

- Total additional claim fee(s) for this application is **\$380**

- **\$90** for **5** total claims over 20.
- **\$290** for multiple dependent claim surcharge.

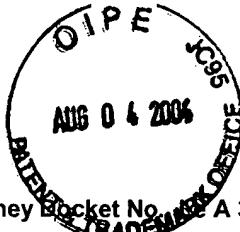
Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

B. S. B.
Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

**ORIGINAL**

Attorney Docket No. A 35 249C1

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

U.S. Application Serial Number: 10/813,801

Filing Date: 03/30/2004

First Named Inventor: Peter Serno

Title: Imidazotriazinone-containing Compositions for Nasal Drug Delivery

Customer No.: 35969

Confirmation No.: 7555

CERTIFICATION OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence and any papers referred to as attached are being deposited, on the date shown below, with the United States Postal Service, with sufficient postage, as first class mail in an envelope addressed to Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: AUG 02 2004

Signature of person certifying

**Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

**RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION
FILED UNDER 37 CFR 1.53(b)**

This replies to the Notice to File Missing Parts of Nonprovisional Application mailed to applicants on 06/22/2004. A copy of the Notice to File Missing Parts is enclosed.

In the Notice to File Missing Parts applicants have been asked to submit the following outstanding fees:

- \$770.00 statutory basic filing fee;
- \$130.00 surcharge fee for late filing of oath or declaration; and
- \$380 fee for additional claims.

Applicants wish to clarify for the record that upon filing of this application on 03/30/2004, applicants submitted a Fee Transmittal (Form PTO/SB/17) authorizing the Commissioner to charge Deposit Account 13-3372 the total amount of **\$1,232.00** for the fees described below:

- \$770 statutory basic filing fee; and
- \$462.00 total claims fee.

In addition to the payment of fees, applicants submitted a copy of the Declaration and Power of Attorney from parent application, USSN 10/122,694 under 37 C.F.R. 1.63(d).

Applicants submit copies of the following documents, which were originally submitted on 03/30/2004:

- Returned itemized postcard bearing the USPTO date stamp;
- Utility Patent Application Transmittal (Form PTO/SB/05) indicating submission of a Fee Transmittal and copy of the declaration from parent application, USSN 10/122,694; and
- Fee Transmittal (Form PTO/SB/17) authorizing the Commissioner to charge Deposit Account No. 13-3372 the total amount of \$1,232.00.

ADDITIONAL CLAIMS FEE(S)

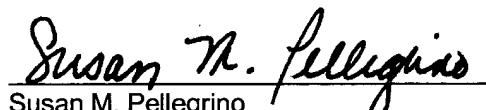
Applicants submit additional claims fee(s) for this application in the amount of **\$380.00** as described below:

- \$90.00 for 5 total claims over 20; and
- \$290 for multiple dependent claim surcharge.

PAYMENT OF FEES

The Commissioner is hereby authorized to charge Deposit Account No. 13-3372 in the amount of **\$380.00** for the matters indicated above. The Commissioner is also authorized to charge any additional fees, any underpayment of fees, and credit any overpayment to the above deposit account. A duplicate of this request is attached.

Respectfully submitted,



Susan M. Pellegrino
Attorney for Applicant(s)
Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, CT 06516-4175

Date: July 30, 2004

Registration No. 48,972

Phone: (203) 812-6450



Jill Durante
Bayer Pharmaceuticals Corp.
Law & Patents
C32-3B
400 Morgan Lane
West Haven, CT 06516



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CB
4/16/04

22581 U.S. PTO
10/813801



033004

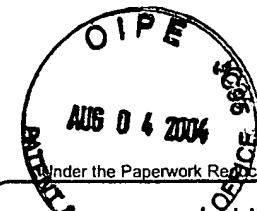
The U.S. Patent & Trademark Office date stamp hereon will acknowledge receipt of the following in Re the application of **Peter Serno, et al.**, Serial No. [to be assigned]; filed herewith, entitled **"Imidazotiazinone-Containing Compositions for Nasal Administration."**

- Utility Patent Application Transmittal;
- Fee Transmittal [IN DUPLICATE];
- Application Data Sheet (4 Pages);
- Copy of Declaration and Power of Attorney from prior application, U.S. Serial No. 10/122,694;
- Copy of prior application, U.S. Serial No. 10/122,694, consisting of 24 pages of specification, 8 pages of claims, and 1 page of abstract;
- Transmittal of Information Disclosure Statement under 37 C.F.R. 1.97(b);
- Information Disclosure Citation (Form PTO-1449); and
- Return Receipt Postcard

Date of Deposit: March 30, 2004
Express Mail Label No. EL844820195US

Docket No. Le A 35 249C1
SMP/jd

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

| | | | |
|--|--|---|--|
| APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents. | | ADDRESS TO: Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450 | |
| 1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) <i>(Submit an original and a duplicate for fee processing)</i> | | 7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) | |
| 2. <input type="checkbox"/> Applicant claims small entity status. <i>See 37 CFR 1.27.</i> | | 8. Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, all necessary)</i> | |
| 3. <input checked="" type="checkbox"/> Specification [Total Pages 33] <i>(preferred arrangement set forth below)</i> <ul style="list-style-type: none"> - Descriptive title of the invention - Cross Reference to Related Applications - Statement Regarding Fed sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings <i>(if filed)</i> - Detailed Description - Claim(s) - Abstract of the Disclosure | | a. <input type="checkbox"/> Computer Readable Form (CRF) | |
| 4. <input type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets _____] | | b. <input type="checkbox"/> Specification Sequence Listing on: | |
| 5. Oath or Declaration [Total Sheets _____] | | i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or | |
| a. <input type="checkbox"/> Newly executed (original or copy) | | ii. <input type="checkbox"/> Paper | |
| b. <input checked="" type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 18 completed)</i> | | c. <input type="checkbox"/> Statements verifying identity of above copies | |
| i. <input type="checkbox"/> DELETION OF INVENTOR(S) <i>Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</i> | | 9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) | |
| 6. <input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | | 10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input checked="" type="checkbox"/> Power of <i>(when there is an assignee)</i> <input checked="" type="checkbox"/> Attorney | |
| | | 11. <input type="checkbox"/> English Translation Document <i>(if applicable)</i> | |
| | | 12. <input checked="" type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS <i>Citations</i> | |
| | | 13. <input type="checkbox"/> Preliminary Amendment | |
| | | 14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <i>(Should be specifically itemized)</i> | |
| | | 15. <input type="checkbox"/> Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> | |
| | | 16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent. | |
| | | 17. <input type="checkbox"/> Other: | |

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

 Continuation Divisional Continuation-in-part (CIP) of prior application No.: 10/122,694.

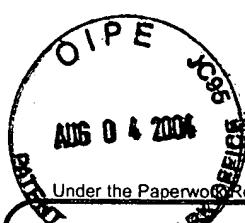
Prior application information: Examiner Mina Haghigheian Art Unit: 1616
 For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

| | | | | |
|--|---|---|----------------|----------|
| <input checked="" type="checkbox"/> Customer Number: 35969 | | OR <input checked="" type="checkbox"/> Correspondence address below | | |
| Name | Jeffrey M. Greenman | | | |
| Address | Vice President, Patents and Licensing Bayer Pharmaceuticals Corporation, 400 Morgan Lane | | | |
| City | West Haven | State | CT | Zip Code |
| Country | US | Telephone | (203) 812-6450 | Fax |
| Name (Print/Type) | Susan M. Pellegrino | Registration No. (Attorney/Agent) | 48,972 | |
| Signature | | | Date | 03/30/04 |

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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FEES TRANSMITTAL

for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 1,232.00)

Complete if Known

| | |
|----------------------|---------------|
| Application Number | |
| Filing Date | |
| First Named Inventor | Peter SERNO |
| Examiner Name | |
| Art Unit | |
| Attorney Docket No. | Le A 35 249C1 |

METHOD OF PAYMENT (check all that apply)

Check Credit card Money Order Other None

 Deposit Account:

| | |
|------------------------|------------------|
| Deposit Account Number | 13-3372 |
| Deposit Account Name | Jeffrey Greenman |

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below Credit any overpayments
 Charge any additional fee(s) or any underpayment of fee(s)
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

| Large Entity | Small Entity | Fee Description | Fee Paid |
|--------------|--------------|--|---------------|
| | | Fee Code (\$) | Fee Code (\$) |
| 1051 130 | 2051 65 | Surcharge - late filing fee or oath | |
| 1052 50 | 2052 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | 1053 130 | Non-English specification | |
| 1812 2,520 | 1812 2,520 | For filing a request for ex parte reexamination | |
| 1804 920* | 1804 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | 1805 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 110 | 2251 55 | Extension for reply within first month | |
| 1252 420 | 2252 210 | Extension for reply within second month | |
| 1253 950 | 2253 475 | Extension for reply within third month | |
| 1254 1,480 | 2254 740 | Extension for reply within fourth month | |
| 1255 2,010 | 2255 1,005 | Extension for reply within fifth month | |
| 1401 330 | 2401 165 | Notice of Appeal | |
| 1402 330 | 2402 165 | Filing a brief in support of an appeal | |
| 1403 290 | 2403 145 | Request for oral hearing | |
| 1451 1,510 | 1451 1,510 | Petition to institute a public use proceeding | |
| 1452 110 | 2452 55 | Petition to revive - unavoidable | |
| 1453 1,330 | 2453 665 | Petition to revive - unintentional | |
| 1501 1,330 | 2501 665 | Utility issue fee (or reissue) | |
| 1502 480 | 2502 240 | Design issue fee | |
| 1503 640 | 2503 320 | Plant issue fee | |
| 1460 130 | 1460 130 | Petitions to the Commissioner | |
| 1807 50 | 1807 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | 1806 180 | Submission of Information Disclosure Stmt | |
| 8021 40 | 8021 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 770 | 2809 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 770 | 2810 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 770 | 2801 385 | Request for Continued Examination (RCE) | |
| 1802 900 | 1802 900 | Request for expedited examination of a design application | |

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity | Small Entity | Fee Description | Fee Paid |
|---------------|---------------|------------------------|----------|
| Fee Code (\$) | Fee Code (\$) | | |
| 1001 770 | 2001 385 | Utility filing fee | 770.00 |
| 1002 340 | 2002 170 | Design filing fee | |
| 1003 530 | 2003 265 | Plant filing fee | |
| 1004 770 | 2004 385 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |
| SUBTOTAL (1) | | (\$ 770.00) | |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|------------------|
| Total Claims | 20 | -20** = 0 | x 18.00 = 0.00 |
| Independent Claims | 5 | -3** = 2 | x 86.00 = 172.00 |
| Multiple Dependent | | | 290.00 = 290.00 |

| Large Entity | Small Entity | Fee Description |
|---------------|---------------|--|
| Fee Code (\$) | Fee Code (\$) | |
| 1202 18 | 2202 9 | Claims in excess of 20 |
| 1201 86 | 2201 43 | Independent claims in excess of 3 |
| 1203 290 | 2203 145 | Multiple dependent claim, if not paid |
| 1204 86 | 2204 43 | ** Reissue independent claims over original patent |
| 1205 18 | 2205 9 | ** Reissue claims in excess of 20 and over original patent |
| SUBTOTAL (2) | | (\$ 462.00) |

**or number previously paid, if greater; For Reissues, see above

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

| SUBMITTED BY | | (Complete if applicable) | | |
|-------------------|---------------------|-----------------------------------|--------|------------------------|
| Name (Print/Type) | Susan M. Pellegrino | Registration No. (Attorney/Agent) | 48,972 | Telephone (203) 812-64 |
| Signature | Susan M. Pellegrino | | Date | March 30, 2004 |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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